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10/575,254	05/08/2007	Masahiro Iwakura	040894-7434	7289
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MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			EXAMINER	
			HAQ, SHAFIQUL	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/575,254	<b>Applicant(s)</b> IWAKURA ET AL.
	<b>Examiner</b> SHAFIQU'L HAQ	<b>Art Unit</b> 1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 9/21/09.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 11-14 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-3 and 5-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement (Form PTO-1448)  
 Paper No(s)/Mail Date 9/14/07 and 11/6/08
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date: \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

***Response to Election-Restriction***

1. Applicants' election without traverse of Group I, claims 1-10 filed September 21, 2009 in response to restriction/election requirement of August 19, 2009 is acknowledged and entered. Applicants' election without traverse of polyarylamine as the support having an amino group with SEQ ID NO: 5 as the defined linker (i.e. R<sub>2</sub>) and SEQ ID NO: 3 as the amino acid sequence (for R<sub>1</sub>) are also acknowledged. Since the election is made without traverse, the restriction/e/election requirement is deemed proper and is made **FINAL**.

Claim 4 does not read on the elected species (polyarylamine has been elected). Accordingly, claims 4 and 11-14 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 1-3 and 5-10 are examined on merits in this office action to the extent that they encompass the elected invention.

***Claim objection***

3. Claims 5 and 8 are objected as being containing non-elected subject matter (i.e. SEQ ID NOs: 1, 2 and 4). Examiner suggests that the non-elected claims cited supra and non-elected subject matter be canceled in response to this Office action to expedite prosecution.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-3 and 5-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claims 1 recites the phrase "said protein or peptide being immobilized at a carboxy end thereof to an insoluble support having a primary amino group via an amide bond mediated by a linker sequence" in lines 3-4. It is unclear as to whether the "carboxy end thereof" is intended to mean carboxy end of the "protein or peptide"? It is also unclear as to whether the "amide bond" is in between the protein and linker sequence or in between the linker sequence and the primary amino group of the support or both the linkages (i.e. the linkages in between the protein and linker sequence and in between the linker sequence and the primary amino group of the support) are via an amide bond. Further, it is unclear what sequence applicants are intended to encompass in the "linker sequence because "sequence" or "linker sequence" is not clearly defined in the specification.
7. With regard to claim 3, the structure of polyarylamine is unclear because "polyarylamine" has not clearly defined in the specification. Specification recites the following on page 19: "As a support in which a polymer compound having a primary amino group in its repeated unit is introduced into an insoluble support, for example, polyarylamine-grafted cellulofine is known (see referential document: Ung-Jin Kin, Shigenori Kuga, Journal of Chromatography A, 946, 283-289 (2003)". However, a review of the reference reveals that the reference teaches **polyallylamine**-grafted cellulose but not **polyarylamine** grafted cellulose and therefore, the structure of the

- polymer encompassed by the phrase "polymer compound having a primary amino group in the repeated structure thereof is polyarylamine" is vague and indefinite.
8. Claim 6 recites "R<sub>2</sub> arbitrarily represent an amino acid sequence of the linker sequence". The claim lacks antecedent basis for the above phrase because the linker sequence of claims 1 is not recited to have an amino acid sequence. Further, it is unclear what is intended to mean by the term "arbitrarily" in the claim. Is the term used to mean that the "amino acid sequence of the linker" and the "support" are subjected to personal will or discretion (i.e. optional) and may not be a part of the claimed invention?
9. With regard to formula (4) of claim 7, it is unclear what part reads on R<sub>2</sub>? R<sub>2</sub> as defined in claim 6 arbitrarily represents an amino acid sequence of the linker sequence. Claim 7 recites "wherein the moiety represented by CO-NH-R<sub>2</sub>-CO in formula (1) is represented by the following formula (4): CO-[NH-CH<sub>2</sub>-CO]<sub>m</sub>-CO, wherein m is a positive integer". Therefore, when m=1 (i.e. a positive integer), the formula (4) would represent CO-NH-CH<sub>2</sub>-CO-CO in which R<sub>2</sub> represents CH<sub>2</sub>-CO and which is not an amino acid. Further, when m=1, it cannot be an amino acid sequence as a sequence must have more than one amino acid unit.
10. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 provides a method for separating and purifying an antibody molecule using the support according to claim 1, but since the claim does not set forth any

steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

***Claim Rejections - 35 USC § 101***

11.35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use of the support of claim 1 for separating and purifying an antibody molecules, without setting forth any active steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd. v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

***Claim Rejections - 35 USC § 102***

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 1-2, 6-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwakura (JP 2000247999).

Claim 1 is directed to a support immobilized thereon a protein or a peptide wherein the protein or peptide is immobilized through its carboxy end to primary amino group on the support via an amide bond by a linker sequence.

Iwakura disclose a support immobilized thereon a protein wherein the protein is immobilized through its carboxy end to a support having an amino group via an amide bond mediated by a linker sequence (see abstract). Iwakura teaches a protein having the formula NH<sub>2</sub>-R<sub>1</sub>-COOH (i.e. having a carboxy end) is attached via an amide bond to a support having an amino group (NH<sub>2</sub>-Y) mediated by a linker sequence (underline portion) NH2-R<sub>1</sub>-CO-NH-CH(CH<sub>2</sub>-SCN)-CO-NH-R<sub>2</sub>-COOH (wherein R<sub>2</sub> is chain of amino acid residues). It is noted a protein is capable of binding to an antibody produced against the protein and therefore, the support so produced would have and affinity to an antibody produced against the protein.

With regard to the preambles "support having an affinity for an antibody" and "support for purifying an antibody", in claims 1, and 9, the preambles are directed to intended use of the claimed invention a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the immobilized protein would be capable of binding to antibody produced against

the protein and thus would have an affinity for antibody against the protein and would be useful as a support for purifying antibody against the protein.

Therefore, the reference is deemed to anticipate the cited claims.

15. Claims 1-2, 6-7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwakura (JP 2000119300).

Claim 1 is directed to a support immobilized thereon a protein or a peptide wherein the protein or peptide is immobilized through its carboxy end to primary amino group on the support via an amide bond by a linker sequence.

Iwakura disclose a support immobilized thereon a protein wherein the protein is immobilized through its carboxy end to a support having an amino group via an amide bond mediated by a linker sequence (see abstract). Iwakura teaches a protein having the formula  $\text{NH}_2\text{-R}_1\text{-COOH}$  (i.e. having a carboxy end) is attached via an amide bond to a support having an amino group ( $\text{NH}_2\text{-Y}$ ) mediated by a linker sequence to provide a protein linked to a carrier represented by formula  $\text{NH}_2\text{-R}_1\text{-CO-NH-R}_2\text{-CO-NH-Y}$  wherein Y is a carrier,  $\text{R}_1$  and  $\text{R}_2$  are amino acid sequence. It is noted a protein is capable of binding to an antibody produced against the protein and therefore, the support so produced would have and affinity to an antibody produced against the protein.

With regard to the preambles "support having an affinity for an antibody" and "support for purifying an antibody", in claims 1, and 9, the preambles are directed to intended use of the claimed invention a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the

prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). In this case, the immobilized protein would be capable of binding to antibody produced against the protein and thus would have an affinity for antibody against the protein and would be useful as a support for purifying antibody against the protein.

Therefore, the reference is deemed to anticipate the cited claims.

***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 5, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over 1) either of Iwakura (JP 2000247999) or Iwakura (JP 2000119300) in view of 2) Yabushita *et al* (JP 05271299) and Colbert *et al* (US 5151350).

See the above teaching of Iwakura for providing a surface having proteins immobilized on the surface wherein the protein being immobilized at a carboxy end thereof to an insoluble carrier having a primary amino group via an amide bond mediated by a linker sequence.

Iwakura does not teach utilizing the protein modified surface for affinity binding of antibody and purification.

Yabushita *et al* teach that immobilization of protein A to a surface provides the surface with unique absorbability with antibody useful for separating and purifying antibody.

Colbert *et al* teach protein-A like material and subfragments thereof having protein A properties of binding to IgG at the Fc region (see abstract) that are useful in the same manner as protein A.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the surface of Iwakura with protein A (Yabushita *et al*) or the protein-A like material and subfragments thereof (Colbert *et al*) with the expectation of affinity purification of antibody (e.g. IgG) with a reasonable expectation of success and the reasonable expectation of success comes from the teaching of Iwakura for attaching a protein to a surface having primary amino group via a linker and form the teaching of protein A (Yabushita and Colbert *et al*) having affinity for antibody (e.g. IgG) useful for separation and purification of antibody. With regard to SEQ ID NO:3 (i.e. elected sequence), Colbert *et al* disclose a sub fragment (see claim 13) having IgG binding and the sequence is the sequence anticipates the sequence of SEQ ID NO:3.

18. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over 1) either of Iwakura (JP 2000247999) or Iwakura (JP 2000119300) in view of 2) Minoura (JP 61015900A).

See the above teaching of Iwakura for providing a surface having proteins immobilized on the surface wherein the protein being immobilized at a carboxy end thereof to an insoluble carrier having a primary amino group via an amide bond mediated by a linker sequence.

Iwakura teaches use of primary amino containing surface for the immobilization but fail to a surface comprising polyarylamine for immobilization of protein.

Minoura teaches cellulose type membrane comprising primary amino group. Minoura teaches that conventional amino containing surface comprises polyaminostyrene (i.e. polyarylamine) (see abstract) and teach that the membrane is highly soft and tough over any other conventional cellulose type membrane and have an excellent function of fixing a physiological active substance such as peptides (see abstract).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to consider utilizing the primary amino containing surface of Minoura for immobilization of proteins using the method of Iwakura with the expectation of providing a support that is flexible but tough with a reasonable expectation of success.

### ***Conclusion***

19. No claims are allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/  
Primary Examiner, Art Unit 1641